

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: TE82969-1-IQR		Iteration No: 01	SAP No: TE0082969QX

INSTALLATION QUALIFICATION REPORT
For the PDA / eLambda Linearity Tester (TE82969-1)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		11 Jul 2018

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		
Eric Turner	Principal Test Engineer		

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

signatures denote

The "Reviewed By" ~~signature(s) denotes~~ agreement with the description of the qualification activities.

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

Version	Author	Summary of change
00	Emma Pierce	First document for approval
01	Luo HuaZhen	Firmware Update

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1.0 Purpose

The PDA / eLambda Linearity Tester (TE82969-1) is located in the Flextronics Contractor Manufacturer site in Singapore. This station is used to verify that linearity of PDA Detectors of the following part numbers is within specification: 186015034, 186015053, 279002224, 279002897, 800000414 and 800000439. The manual firmware download for these part numbers is most commonly done at the TE82969 system although it is unrelated to the Linearity and Wavelength Accuracy tests that are the primary purpose of the PDA/eLambda Linearity Test System. After the instrument firmware download is complete, the UUT undergoes wavelength calibration using custom software at the TE82969 system, then it is moved to the 2998 Final Test System (TE82882) to test noise, drift, and optics.

This Installation Qualification is being performed as required by the Validation Assessment Form TE82969-06JUL2018-VAF which can be found in the TE0082969QX directory of SAP.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the PDA / eLambda Linearity Tester (TE82969-1) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-06JUL2018-VAF.

This Installation Qualification Report defines the documents used to qualify the PDA / eLambda Linearity Tester (TE82969-1).

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA / eLambda Linearity Tester was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-06JUL2018-VAF. All required Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the PDA / eLambda Linearity Tester complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the PDA / eLambda Linearity Tester (TE82969-1) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
BOM	Bill of Materials not used
CAL/PM	Calibration/Preventive Maintenance not used
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
N/A	Not Applicable
P/N	Part Number
PC	Personal Computer not used
PDA	Photo Diode Array
SAP	Enterprise Resource Planning Software
S/N	Serial Number
TSP	Test Specification and Procedure
UUT	Unit Under Test
VAF	Validation Assessment Form

Template 730002845, Version 02
 Ref. 730001835, Process Validation Procedure for Milford Site

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ECR Engineering change Request

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5.0 Training

The operator of the PDA / eLambda Linearity Tester (TE82969-1) was trained according to the UPC2 PDA and Veyron PDA Final Test Procedure 735002531, Ver. 09. The executors of this qualification were trained according to the Installation Qualification Procedure 730004135, Ver. 00. Both training records are provided as Attachment 7.1 and 7.2, respectively.

6.0 Qualification Results

- 6.1 Test Script IQ-01: Associated Documentation Verification, Test Script IQ-02: Site Verification, and Test Script IQ-03: Instrumentation Calibration Verification were not performed according to Validation: **TE82969-06JUL2018-VAF**
- 6.2 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.
- 6.2.1 The TE82969 Test Equipment Software version listed in UPC2 PDA and Veyron PDA Final Test Procedure 735002531, Ver. 09 is Test Software 2.0 and was verified to match the version listed on the Test Record. The Test Record is provided as Attachment 7.4 and 7.5.
- 6.2.2 The firmware version listed in ECR #9222852 for part numbers 186015034 and 186015053 is 1.70.6367 and was verified to match the version listed on the Test Record. The test records are provided as Attachments 7.4 and 7.5.
- 6.3 Test Script IQ-05: General Safety and Alarms was not performed according to TE82969-06JUL2018-VAF.
- 6.4 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.6.
- 6.4.1 One (1) UUT (P/N: 186015034, S/N: G18C2P393A) was tested using the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.7 for the passing Test Record.
- 6.4.2 One (1) UUT (P/N: 186015053, S/N: G18ADT145A) was tested using the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.8 for the passing Test Record.
- 6.5 This table provides a summary of each test script as performed according to 730004135, Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-04	Pass	Attachments 7.4, and 7.5	None
IQ-06	Pass	Attachments 7.7 and 7.8	None

7.0 Attachments

- 7.1 Completed Operator Training Record 735002531, Ver. 09
- 7.2 Completed Executor Training Record 730004135, Ver. 00
- 7.3 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.4 Objective Evidence IQ-04: Passing Test Record for UUT Part #186015034 (G18C2P393A)
- 7.5 Objective Evidence IQ-04: Passing Test Record for UUT Part #186015053 (G18ADT145A)
- 7.6 Completed Test Script IQ-06: Functional Verification
- 7.7 Objective Evidence IQ-06: Passing Final Test Record for UUT Part #186015034 (G18C2P393A)
- 7.8 Objective Evidence IQ-06: Passing Final Test Record for UUT Part #186015053 (G18ADT145A)

I marked each reference to the test record Attachments → see email note

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8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification Procedure 730004135, Ver. 00.

9.0 References

The current approved versions of the following documents are referenced within this report:

Document Number	Document Title
730004135, Ver. 00	Installation Qualification Procedure
735002531, Ver. 09	UPC2 PDA and Veyron PDA Final Test Procedure
735003437, Ver. 00	PDA Linearity Test System PM Procedure Not Used
721007811, Ver. 01	2898 PDA Detector Functional Specification Not Used
TE0082969QX	Validation Assessment Form TE82969-06JUL2018-VAF
TE0082969QX	Installation Qualification TE82969-1-IQR-Iteration 01
ECR #9222852	Engineering Change Request for Firmware Release

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Title: individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	Luo Huazhen	Employee ID ¹	618078
Date of Training	18 Apr 2018		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	00


 Employee's Signature _____ Title Senior Test Engineer 18 Apr 2018
 Date

 Trainer's Signature _____ Title N/A - self trained 18 Apr 2018
 Date

Document No.: TE82969-1-IQR
 Iteration No.: 01
 Attachment: File Page: 1 of 1

¹ Without preceding "90"

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82969-1		Equipment Name: PDA/ eLambda Linearity Test System		
Installation Site: Flextronics: WPPL, Singapore				
Purpose: To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents). Test Execution: List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable. Objective Evidence: Completed Test Script Data Sheet Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.				
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date
Firmware Version P/N: 186015034	Version: 1.70.6367	Version: 1.70.6367	Pass	H2 11Jul2018
Firmware Version P/N: 186015053	Version: 1.70.6367	Version: 1.70.6367	Pass	H2 11Jul2018
Comments: Firmware versions specified in ECR #9222852 N/A H2 11Jul2018				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Copy this Test Script as needed

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Template 730000483 V06

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Document No.: TE82969-1-IQR
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 Attachment: 7.3 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015034

Operator: 246112

Serial Number: G18C2P393A

Test System: TE82969-1

Test Software: 2.0

Product: Acquity UPC2 PDA

Start Time: 07/10/2018, 16:47:

End Time: 07/10/2018, 16:56:

Order: NA

Location: Flextronics,SG

TMD: NA

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	3.885	5		PASS
Mean		0.088			PASS
Std Dev		0.003			PASS
Lambda		257.74			PASS
A/C 5mg		0.0852			PASS
A/C 10mg		0.0903			PASS
A/C 15mg		0.0924			PASS
A/C 20mg		0.0903			PASS
A/C 25mg		0.088			PASS
A/C 30mg		0.0833			PASS

Acquity UPC2 PDA Linearity Test Overall Result - PASS

Signed: [Signature]

Date: 10 Jul 2018

END OF DATA

These should match

Document No.: TE82969-1-IQR
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Attachment: 7.4 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015053

Product: Acquity Tapered Slit PDA

Operator: 246112

Start Time: 07/10/2018, 15:59:

Serial Number: G18ADT145A

End Time: 07/10/2018, 16:05:

Test System: TE82969-1

Order: NA

Test Software: 2.0

Location: Flextronics,SG

TMD: NA

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	4.267	5		PASS
Mean		0.088			PASS
Std Dev		0.004			PASS
Lambda		257.48			PASS
A/C 5mg		0.0853			PASS
A/C 10mg		0.0907			PASS
A/C 15mg		0.0928			PASS
A/C 20mg		0.0907			PASS
A/C 25mg		0.0885			PASS
A/C 30mg		0.0828			PASS

Acquity Tapered Slit PDA Linearity Test Overall Result - PASS

Signed: Q

246112

Date: 10 Jul 2018

END OF DATA

→ Training record
for this operator?

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Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82969-1		Equipment Name: PDA/ eLambda Linearity Test System	
Installation Site: Flextronics: WPPL, Singapore			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality. Test Execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable. Objective Evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance Criteria	Pass/Fail	Initial & Date
UUT Part Number: 186015034 UUT Serial Number: G18C2P392A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
UUT Part Number: 186015053 UUT Serial Number: G18ADT145A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
Comments: N/A HZ 11 Jul 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

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Template 730000483 V06

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 Attachment: 7.6 Page: 1 of 1

WATERS CORPORATION INSTRUMENT - FINAL TEST RECORD

Part Number: <u>186015034</u>	Description: <u>ACQUITY UPLC2 PDA DETECTOR</u>
Tested By: <u>KWEEK CHECK MERRY</u>	Date: <u>10 JUL 2018</u>
Serial Number: <u>618C2P393A</u>	Control Number: <u>NA</u>
Software Revision: <u>1.70.6367</u>	Factory Order: <u>NA</u>

Electrical Safety

PASS ☒ FAIL ☐ see note # PASS ☐

FANS

PASS ☒ FAIL ☐ see note # PASS ☐

LED'S FUNCTIONALITY

PASS ☒ FAIL ☐ see note # PASS ☐

Linearity (% RSD) Actual: 3.88

PASS ☒ FAIL ☐ see note # PASS ☐

Wavelength Accuracy

255nm 254.7 379 378.5 523 522.7

PASS ☒ FAIL ☐ see note # PASS ☐

Final Test

PASS ☒ FAIL ☐ see note # PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed L. 842.15 Date: 11 JUL 2018

Notes: NA → should initial anal date

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.

END OF DATA

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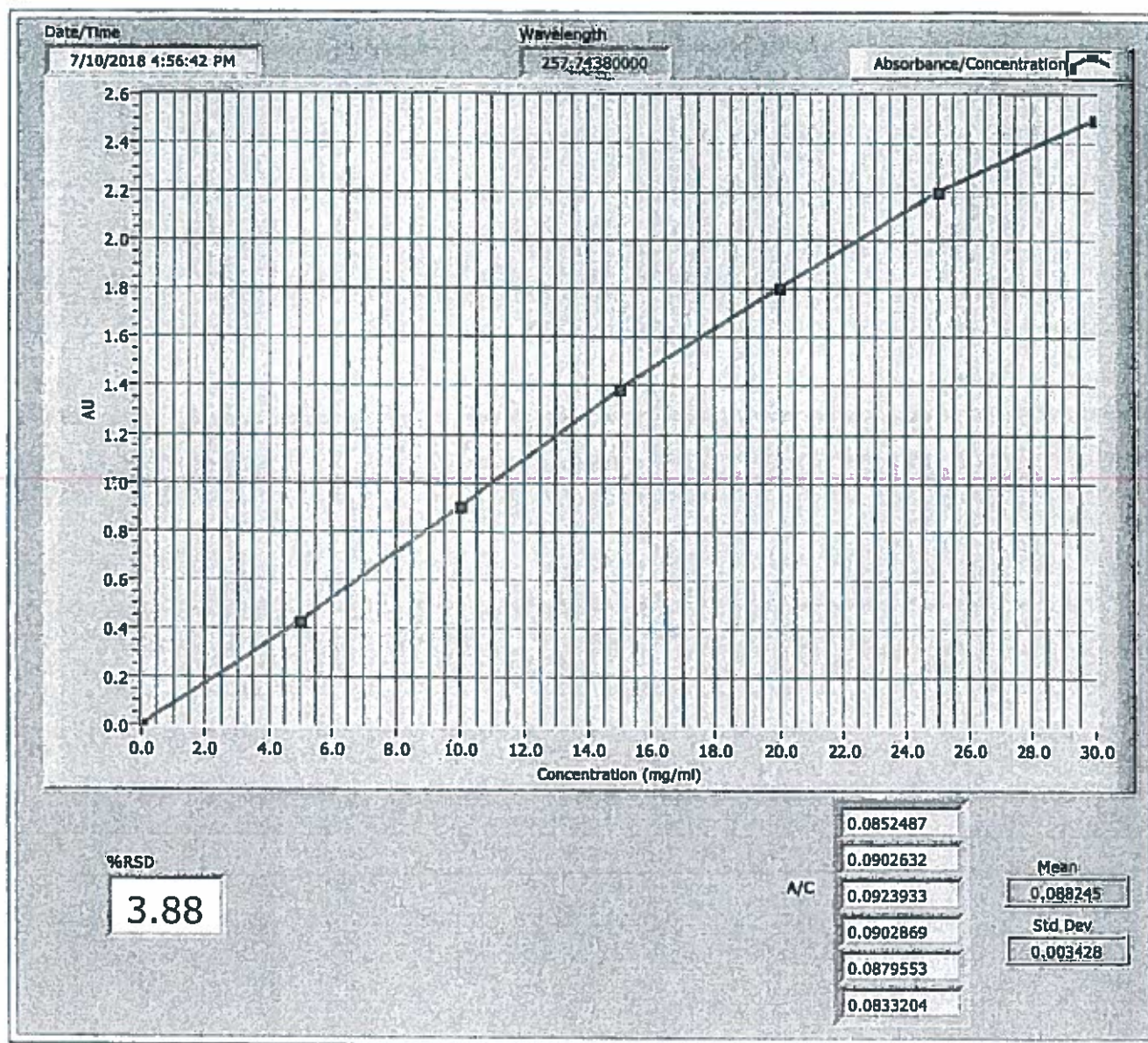


Linearity Graph

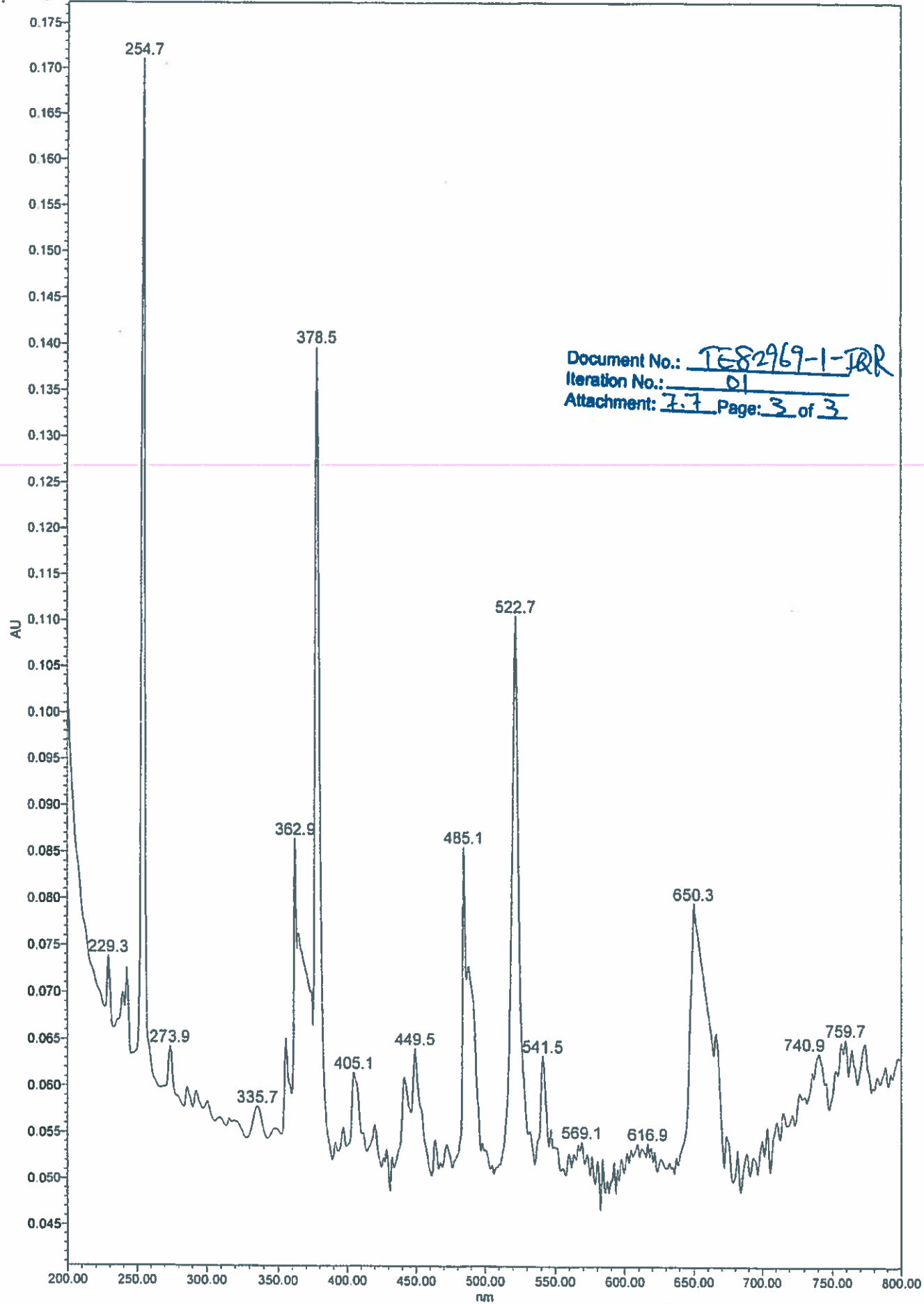
C:\Program Files\PDA Lin\PDA Linearity.exe\CrunchData.vi

Last modified on 7/10/2018 at 4:56 PM

Printed on 7/10/2018 at 4:56 PM



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WATERS CORPORATION
INSTRUMENT - FINAL TEST RECORD

Part Number: <u>186015053</u>	Description: <u>ALQUITY PDA DET-W TAPER SLIT</u>
Tested By: <u>KWEK CHOLE MENLY</u>	Date: <u>10 / JUL / 2018</u>
Serial Number: <u>G18 ADT 145A</u>	Control Number: <u>NA</u>
Software Revision: <u>1.70.6367</u>	Factory Order: <u>NA</u>

Electrical Safety

PASS ☒ FAIL ☐ see note # PASS ☐

FANS

PASS ☒ FAIL ☐ see note # PASS ☐

LED'S FUNCTIONALITY

PASS ☒ FAIL ☐ see note # PASS ☐Linearity (% RSD) Actual: 4.27PASS ☒ FAIL ☐ see note # PASS ☐

Wavelength Accuracy

255nm 254.4 379 378.8 523 523.0PASS ☒ FAIL ☐ see note # PASS ☐

Final Test

PASS ☒ FAIL ☐ see note # PASS ☐Instrument Result: PASS ☒ FAIL ☐ Signed L f 2185 Date: 10 / JUL / 2018Notes: NA → initial and date

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END OF DATA

+ CORRECTION OF WRONG ENTRY L f 2185 11 JUL 2018

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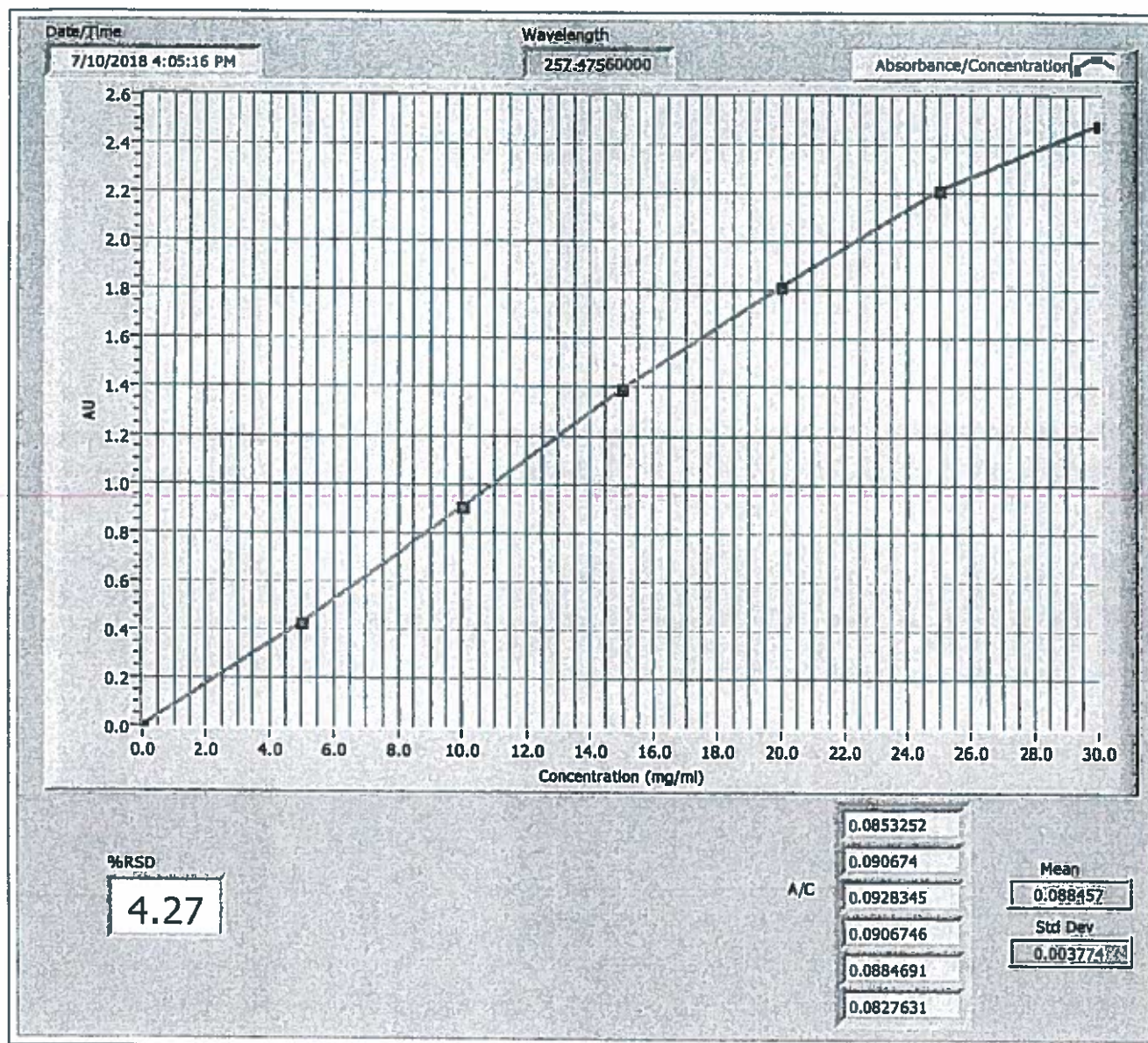


Linearity Graph

C:\Program Files\PDA Lin\PDA Linearity.exe\CrunchData.vi

Last modified on 7/10/2018 at 4:05 PM

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Document No.: TES2969-1-12R

Iteration No.: 01

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